DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94134d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 2939281

July 11, 2003

Frank P. Barcellos, Partner
Liduina Barcellos, Partner
Frank and Liduina Barcellos Dairy
14581 Road 80
Tipton, CA 93272-9777

WARNING LETTER

Dear Mr. and Ms. Barcellos:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your dairy. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation May 5 & 6, 2003. This inspection revealed serious violations of Sections 402(a)(2)(C)(ii), 402(a)(4) and 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). .

On February 19, 2003, you consigned a dairy cow, with [redacted] back tag number 8898, last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 441848) collected from that animal identified the presence of the drug penicillin in the kidney at 1.76 parts per million (ppm). Presently, the tolerance level for penicillin in the uncooked edible tissue of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510). Your use of penicillin in the animal resulted in the illegal drug residue found in the kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

1. You lack complete, permanent written medication treatment records for lactating dairy cows. Your treatment records fail to include the amount of drug administered, the withdrawal times for the meat, and the specific days the drug are administered.

2. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling or your veterinarian's prescription labeling. The labeled directions for the Agrapharm brand Pen-Aqueous Penicillin G Procaine is 3000 units, or one (1) ml, per 100 pound body weight. You administer 20 to 35 ml of Pen-Aqueous twice daily (40 – 70 ml daily). In addition, the labeling states not to exceed 10 ml per injection site. You administer the 20 – 35 ml of the drug all in one site.

3. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating Pen-Aqueous brand penicillin G within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. The manufacturer's label specifies a daily dose of 1 ml per 100 pounds of bodyweight and a maximum dosage of 10cc per site. Your practice of injecting 20 to 35 ml, twice daily, all in one site results in a dosage in excess of that allowed in the labeling. This overdosing presents a possibility that illegal residues will occur.

In addition, you are adulterating the drugs Amoxi-Mast amoxicillin and Oxymycin 200 oxytetracycline injection within the meaning of Section 501(a)(5) of the Act in that you are failing to use these drugs in conformance with their approved labeling. Your veterinarian's label prescribes a withdrawal time of twelve (12) days for the Amoxi-Mast, however, a cow identified with ear tag # 1093 was consigned for slaughter for human food seven days after the last treatment with Amoxi-Mast. The manufacturer's labeling for the Oxymycin 200 directs that the drug be administered intramuscular. You are administering this drug intravenously and you do not have a veterinarian's prescription for this route of administration.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it

was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District

cc: [redacted]